

Redesigning Liver Distribution: - *Survey Results*

*OPTN Liver and Intestinal Organ Transplantation Committee
September, 2014*

OPTN
UNOS

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Executive Summary

The goal of this survey was to get broad-based feedback from the transplant community (including transplant centers, organ procurement organizations, and the general public) regarding liver redistricting as a means to reduce the variation in candidates' MELD scores at transplant.

Almost 700 responses (N=694) were received, with 45% coming from transplant centers. Of the 694 responses, 194 did not provide a state affiliation. Because of the open nature of the survey design, some states responded more often than others, and some states did not respond, despite having an active liver transplant program. In an attempt to address these issues of non-parity, analysis was completed for some of the questions in two formats: weighted¹ and un-weighted. Weighted results did not differ substantially from the un-weighted results, but did lower the mean slightly towards agreement. To the extent that those states with a larger number of responses appear to represent one end of the spectrum (either strongly support or strongly oppose), these responses seemed to counterbalance each other (see graphs for Questions 2 and 4).

Nearly 80% of respondents either strongly agreed or agreed that the ability of all patients to receive timely access to liver transplantation is a component of a fair national organ transplant system (Question 1). Nearly two-thirds of the respondents (63%) felt that addressing the geographic disparity in liver allocation should be a top priority for the OPTN (Question 2). If the current liver distribution were to change, 96% of respondents thought that maximizing transplant survival benefit was either very important or somewhat important, while 94% said that optimizing the quality of life for liver recipients was either very important or somewhat important (Question 3). Similar results were also seen for having fewer deaths on the waiting list (89.7%), maximizing the number of patients transplanted (82.3%), and reducing the variation in severity of illness at transplant (78.9%).

More than half of respondents (57.4%) would support creating larger distribution areas, as long as issues such as cold ischemia times, cost, inappropriate discards, or other operational issues were addressed (Question 4).

The majority of respondents in four regions (1, 5, 6 and 9) were in favor of a 4-district map, while 2 regions were in favor of an 8-district map. The majority of respondents in four other regions were in favor of no change to liver distribution. Of all respondents, 19% were in favor of fewer than 4 districts, 33.6% were in favor of 4 districts, 29.7% were in favor of 8 districts, and 16% were in favor of an alternative proposal. About one-third stated that there was no need for change (each respondent could select more than one option).

Over 87% of respondents were either very concerned or somewhat concerned about discards that could result from a revised allocation policy (Question 6), and 83% were either very concerned or somewhat concerned about the logistics resulting from the policy change. Other concerns (in decreasing order of importance) were: increased proportion of high MELD candidates transplanted (79%), incomplete communication between OPOs and transplant centers (77%), financial issues (75%), implications for OPO performance (72%), and inadequate evidence basis for re-drawing new distribution areas (69%).

¹Among those states that provided a response, we adjusted results according to the proportion of registrants who were listed for a liver in that state. We made a similar adjustment according to the region of the responder.

Regions expressed varied opinions and the results sometimes demonstrated a divergence of opinion within the same region. For example, the mean response² for Question 2 (Addressing the geographic disparity in liver distribution should be a top priority for the OPTN) ranged from 1.17 to 4.24. While the responses from states within Regions 1, 2, 4, 5, 9, and 10 were generally in agreement, and the states in Region 8 were typically not in agreement, there was a diversity of opinion from the states in Regions 3, 6, 7, and 11. Similarly, the mean response for Question 4 (support for creating larger distribution areas) ranged from 1.2-1.5 among regions 1, 5, and 9. On the other hand, the mean response to this same question varied from 3.3 to 4.4 among regions 3, 7, 8 and 11. Within Region 8, the mean response by state ranged from just over 3 (about neutral) to 5 (strongly disagree). Within Region 3, the mean response by state ranged from 2 (somewhat agree) to nearly 4 (somewhat disagree).

Overall, there was consensus that all liver transplant candidates should receive timely access to transplants, and that reducing geographic disparities should be one of the primary goals of the OPTN. Further, more than half of the respondents agreed that creating larger distribution areas was one way to achieve this goal. While 32% of the respondents felt that no change in distribution areas is necessary, 47.7% indicated that a system with either 4 or 8 districts would be acceptable, and 55.8% indicated that either fewer than 4 districts, or 4 or 8 districts would be acceptable.

The OPTN Liver and Intestinal Organ Transplantation Committee members will further discuss the survey results at the national liver forum on September 16, 2014 in Chicago.

² Lower mean responses indicate more agreement with the survey statement.

Introduction

The Organ Procurement and Transplantation Network (OPTN) manages all aspects of organ donation and transplantation. One of the OPTN's roles is to develop policy that best serves the needs of all patients nationwide. The existing liver transplantation system meets many of those needs and has been repeatedly improved over time. However, there are significant geographic differences in how sick people must be before they get transplanted. The OPTN's Liver and Intestinal Organ Transplantation Committee has investigated a number of approaches to reduce this geographic disparity. Any new approach must be balanced against potential undesirable effects such as increases in organ preservation time, costs related to organ preservation and transportation, and organ discards.

As an alternative to existing local/regional liver distribution³, a method under consideration is to create new distribution districts that are mathematically optimized to reduce the variation in a candidate's MELD⁴ score at transplant. The committee prepared a concept paper describing this approach and made it widely available to the transplant community on June 16, 2014. The concept paper included a brief survey, the purpose of which was to gather feedback from the transplant community in advance of the national public forum on liver redistricting scheduled for September 16, 2014 in Chicago. This report summarizes the survey responses.

Survey Design

The survey was widely distributed to transplant centers, organ procurement organizations, other OPTN members, and the general public. It was also posted to a survey link on the OPTN, UNOS, and TransplantPro websites (a copy of the survey tool can be found in appendix B). Twelve questions were designed to gauge the transplant community's opinions on the way deceased donor livers are currently distributed and their receptiveness to potential changes. The survey also included open-ended questions to give respondents an opportunity to identify new issues and make suggestions. Survey questions 1, 2, and 4 included statements to which the respondents could answer "Strongly Agree", "Somewhat agree", "Neutral", "Somewhat disagree", or "Strongly disagree". The percentage of respondents that selected each of these options are provided in the results section. Each response was converted to a numeric value, where 1 = strongly agree and 5 = strongly disagree so that mean values could be computed for comparison.

- Question 3 listed 5 key goals that could be potentially addressed by changing the distribution system. Respondents were asked how important each goal was to them ("Very important", "Somewhat important", "Neutral", "Somewhat unimportant", and "Very unimportant").
- Question 5 asked respondents if they would support developing revised policy that uses geographic units with fewer than 4 districts, 4 districts, or 8 districts, with options for "Alternate proposals" and "No change needed." Respondents could select multiple options for this question.
- Question 6 listed seven areas of potential concern related to increasing the size of the distribution areas. The possible responses were "Very concerned", "Somewhat concerned", "No opinion", "Somewhat unconcerned," and "Not at all concerned."
- Questions 7–9 asked for other potential solutions, observations or comments. Those comments were analyzed to identify potential forum agenda items and to gauge the overall support for the concepts.

³ For information about the current distribution policy, please see:
http://optn.transplant.hrsa.gov/ContentDocuments/OPTN_Policies.pdf#nameddest=Policy_09

⁴ The Model for End-Stage Liver Disease (MELD) is a score ranging from 6 to 40 that indicates a candidate's degree of medical urgency while on the waiting list. A candidate with a MELD of 40 is much more likely to die without a liver transplant than a candidate with a score of 6.

Responses

The concept paper and accompanying survey were released on June 16, 2014 and survey responses were collected through July 11, 2014. A total of 694 responses were received from the following categories:

- Transplant Hospital: 45% (64 hospitals representing 47% of all liver transplant programs)
- OPO: 7%
- Other OPTN member: 2%
- Other Public: 9%
- Patient or family: 9%
- No affiliation provided: 28%

Strengths of Survey Results

- Sizable response
- Completeness of response to primary questions
- Numerous responses to open-ended questions

Limitations

1. Some respondents exited the survey before completing it (30%) and did not answer the open-ended or demographic questions. Others failed to identify their state/affiliation/institution (n=194); those results could not be included in the tabulations by state or region.
2. A disproportionate number of responses received from some states could unduly influence the overall results.

Methods for Addressing Potential Issues

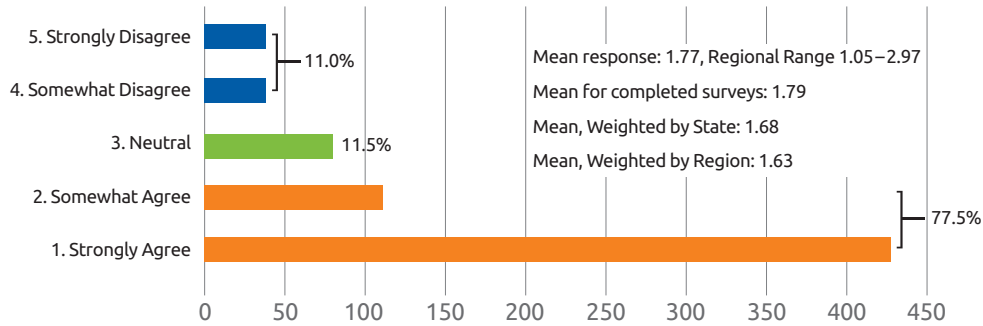
1. **Completeness:** Consideration was given to including only completed surveys, however this would have meant excluding 30% of the survey data. Instead, all responses were included in the aggregate tabulations.
2. **“Disproportionate” response by some states.** The survey was intentionally sent to a large and diverse audience, with no attempt to create a representative sample akin to a scientific poll. In order to illustrate the impact of a large number of responses made by a few states, results are provided in the following ways:
 - Aggregate results, as well as separate tabulations illustrating the impacts of states with large responses;
 - Results by state within each region;
 - Weighted responses by state and region. Weights by state were based on the proportion of patients on the liver waiting list at each center as of June 30, 2014. Survey responses were then adjusted to reflect those percentages. Similar weights were created for each region.

Results

Question 1.

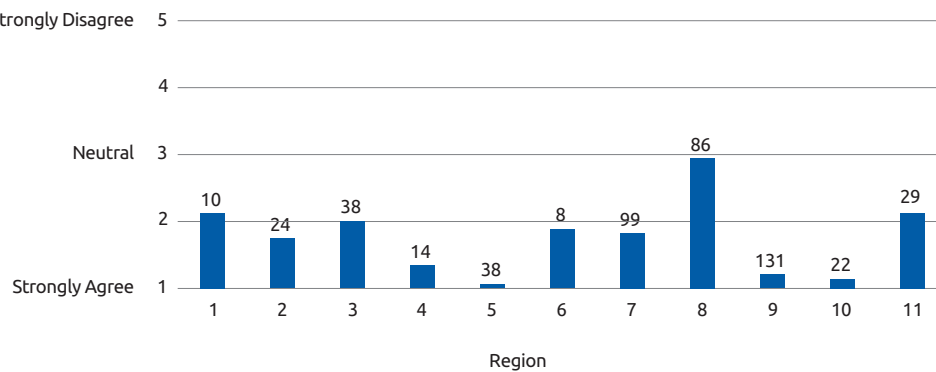
“The ability of all liver transplant candidates to receive timely access to liver transplantation is a component of a fair national organ transplant system.”

Figure 1A: Overall Response



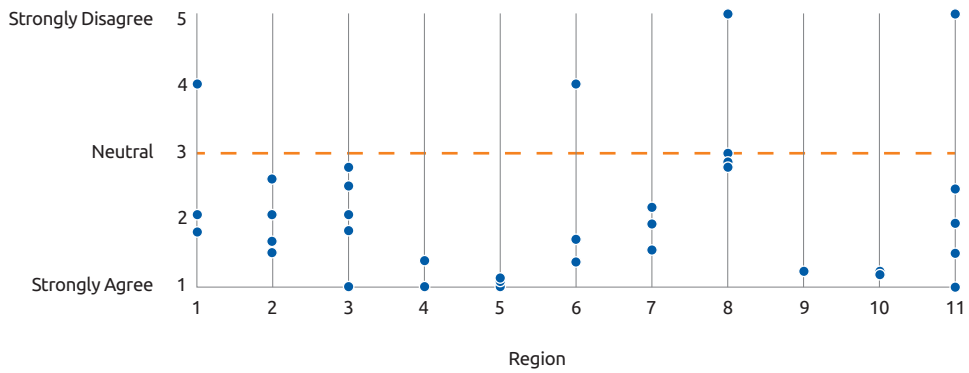
As Figure 1A suggests, there appears to be a high degree of agreement with this statement. Greater than 77% of the respondents either strongly agreed or somewhat agreed that timely access to liver transplantation is a component of a fair national organ transplant system. On a numerical scale, the table shows the overall mean response, along with the mean for various weighting scenarios. For this question, the weighting scenarios did not substantially impact the overall mean of 1.77.

Figure 1B: By Region



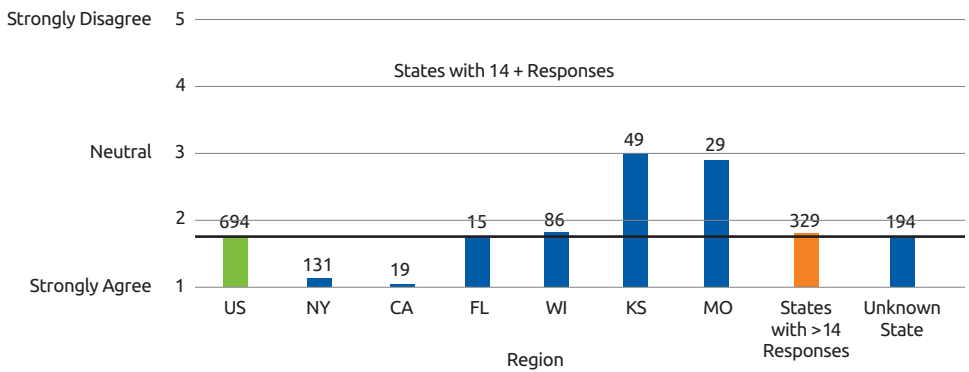
Note that the mean response across regions (Fig 1B) ranged from about 1 (Strongly Agree) to 3 (Neutral).

Figure 1C: By State, within Region



The numbers on top of the bars indicate the total number of responses for that region. The response by state was consistently in support for states within Regions 2, 3, 4, 5, 7, 9, and 10 (Fig 1C). Each dot represents a state average within a given region.

Figure 1D: Specific Individual State Responses



Among individual states with at least 14 responses (Fig 1D), most were in agreement (mean ≤ 2), while others were neutral (mean approximately 3). As a group, the response from these states was similar to the overall US mean.

Question 2.

“Addressing the geographic disparity in liver distribution should be a top priority for the OPTN.”

Figure 2A: Overall Response

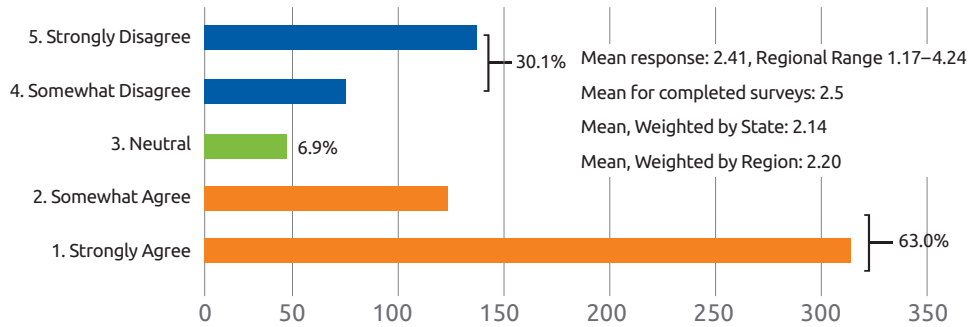
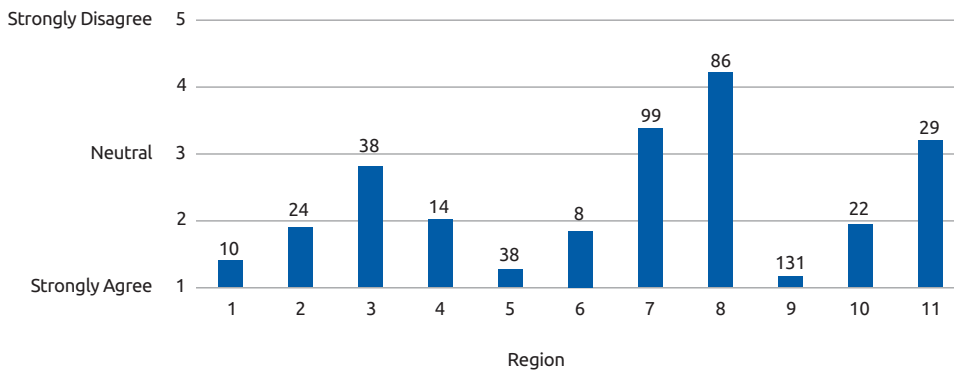


Figure 2A shows that 63% of the respondents felt that addressing geographic disparity in liver distribution should be a top priority of the OPTN, while about 30% either somewhat disagreed or strongly disagreed with this statement.

Figure 2B: By Region



On a numerical scale, the overall mean in the US was 2.4, while mean response across regions ranged from about 1.2 to 4.2 (Figure 2B).

Figure 2C: By State, within Region

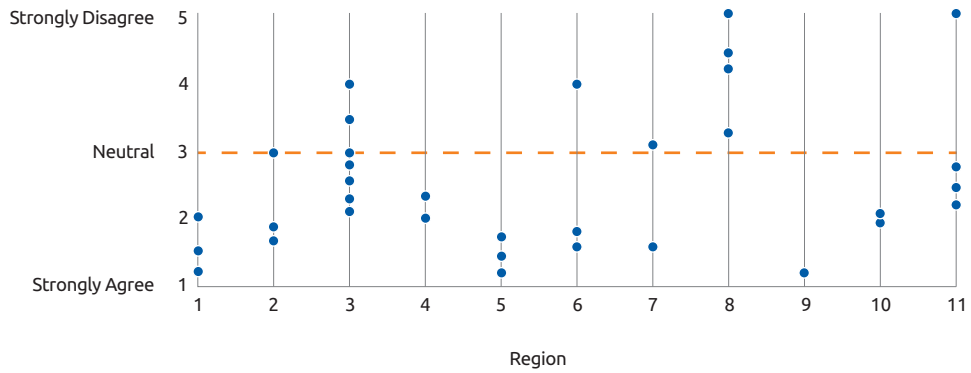
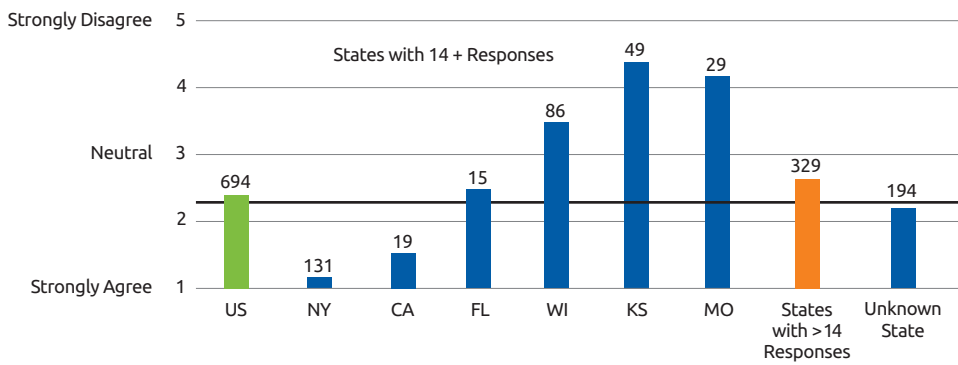


Figure 2C shows considerable variation in the responses among states within a particular region.

Figure 2D: Specific Individual State Responses



Among individual states with at least 14 responses (Fig 2D), some were in disagreement (mean > 4), while others in agreement (mean < 2). As a group, the response from these states was higher than the overall US mean.

Question 3.

“If the current distribution system were to change, how important are the following goals?”

Figure 3

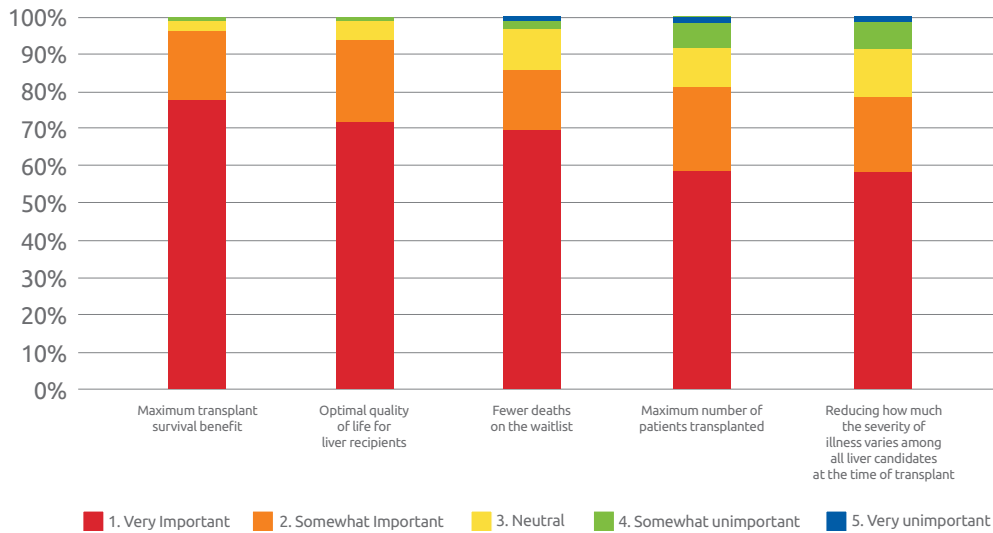


Figure 3 shows that over 96% of respondents thought that maximizing transplant survival benefit would be an important goal of a new distribution system. Similarly, over 94% felt that having optimal quality of life for liver recipients would be important. Fewer deaths on the waitlist (89.7%), maximizing the number of patients transplanted (82.3%), and reducing the variation in the severity of illness (78.9%) were also deemed important.

Question 4.

“In an effort to achieve these goals, I support creating larger distribution areas, as long as the proposal addresses issues (cost, cold ischemia time, inappropriate discards, and operational challenges).”

Figure 4A: Overall Response

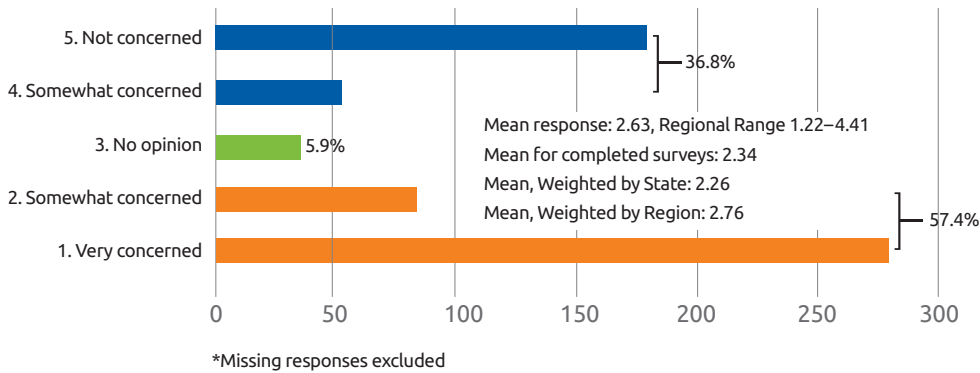
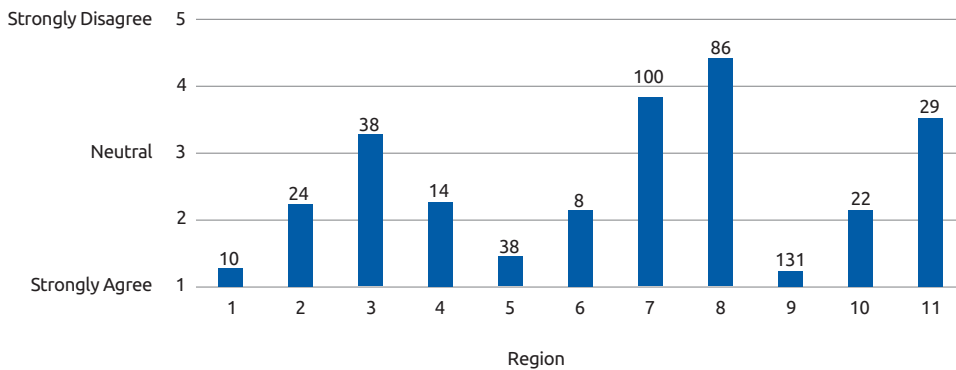


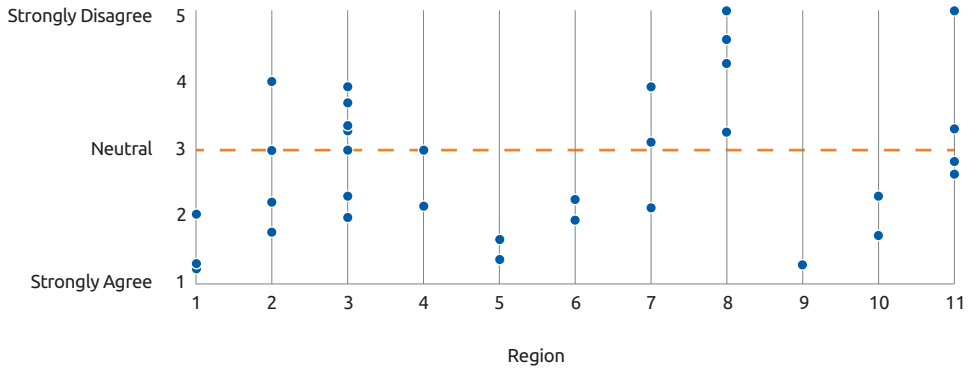
Figure 4A shows that over 57% of respondents were in favor of creating larger distribution areas, assuming that such issues as cost, cold ischemia time, and increasing discards could be addressed.

Figure 4B: By Region



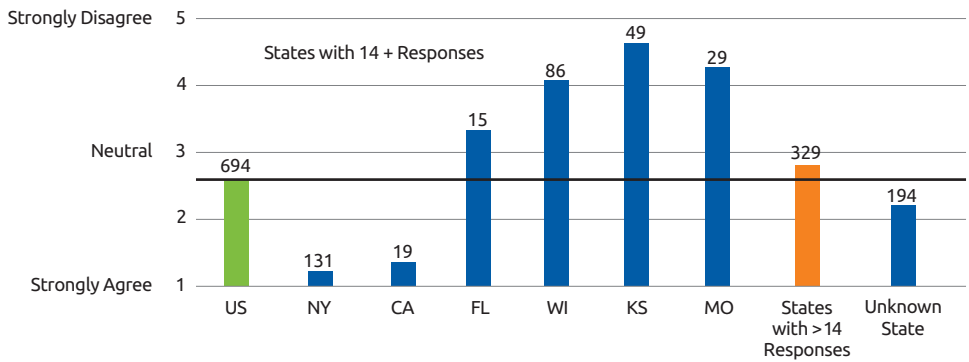
This translates to a mean response of 2.6, with a range of 1.2 to 4.4 across regions (4B).

Figure 4C: By State, within Region



As Figure 4C indicates, responses varied by state within most of the regions.

Figure 4D: Specific Individual State Responses

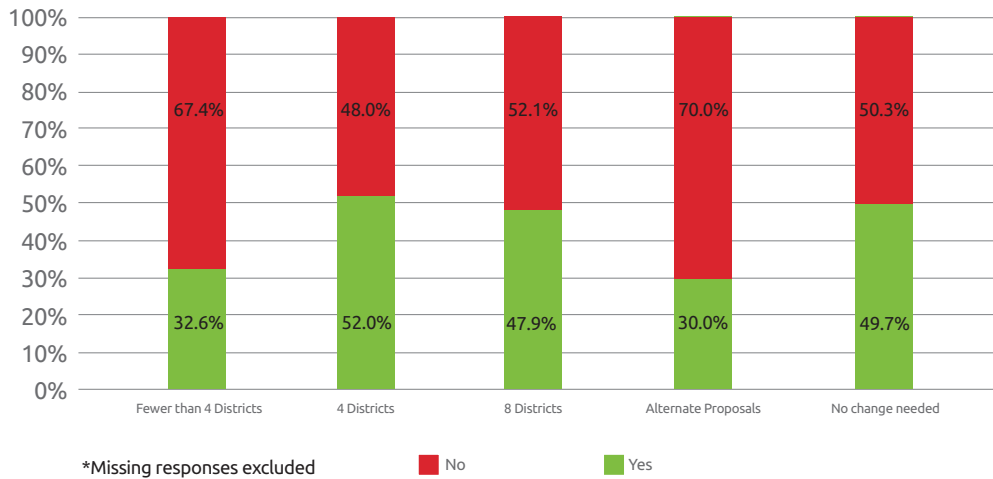


Four states with more than 14 responses were not in favor of creating larger distribution areas, while 2 states in this group supported the concept (Fig 4D).

Question 5.

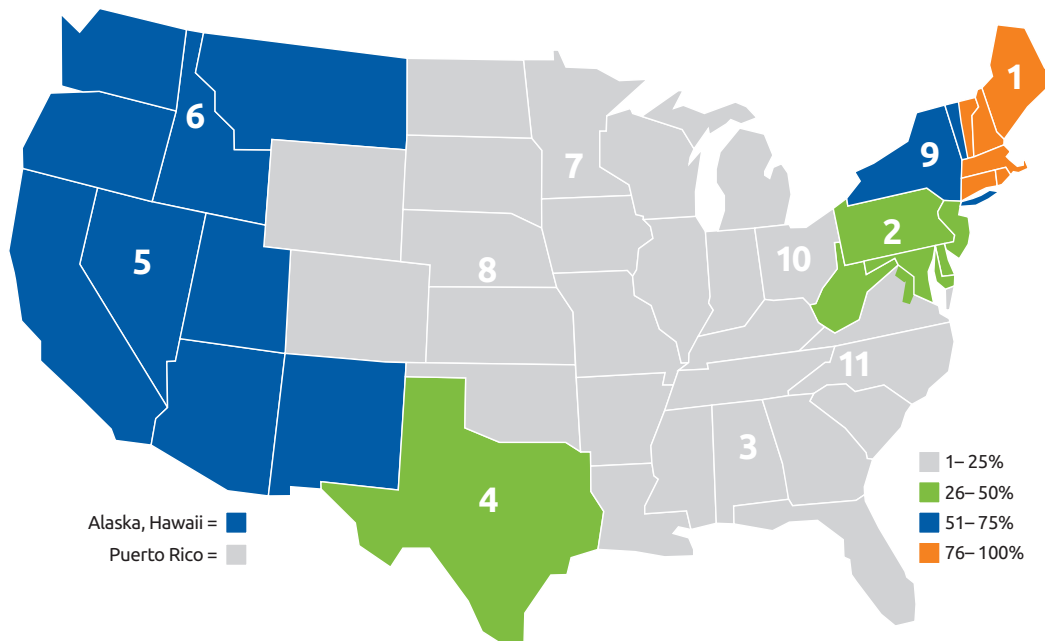
I would support developing revised policy that uses geographic allocation units (Fewer than 4 Districts, 4 Districts, 8 Districts, Other, No change needed)

Figure 5A: Overall Response



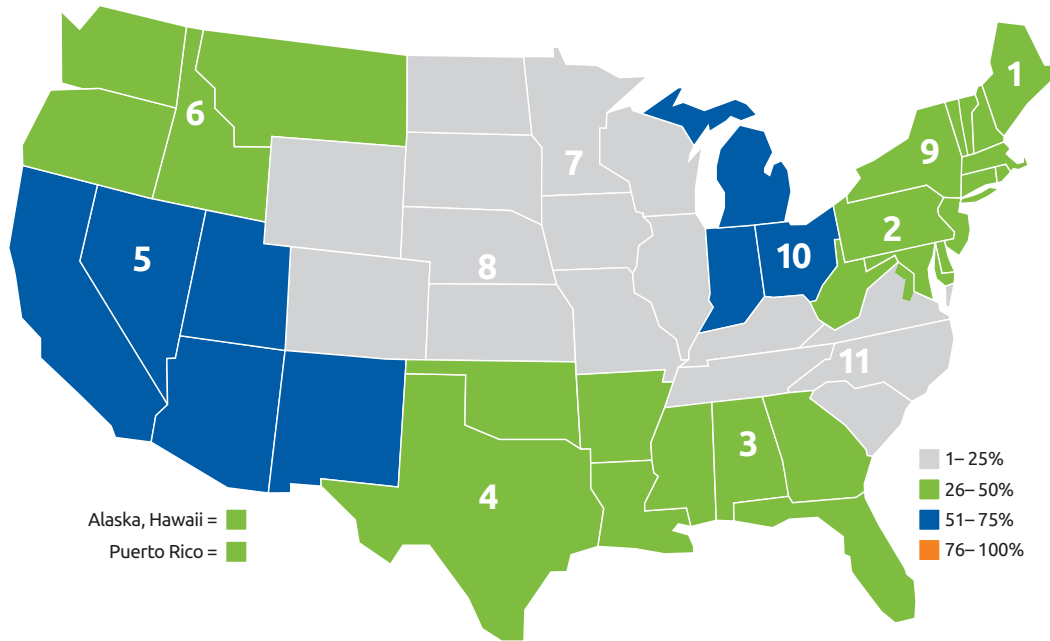
Overall, respondents had mixed support for developing policy that would use geographic allocation units, ranging from 30% for alternate proposals to 52% support for 4 districts (Figure 5A).

Figure 5B: 4 Districts



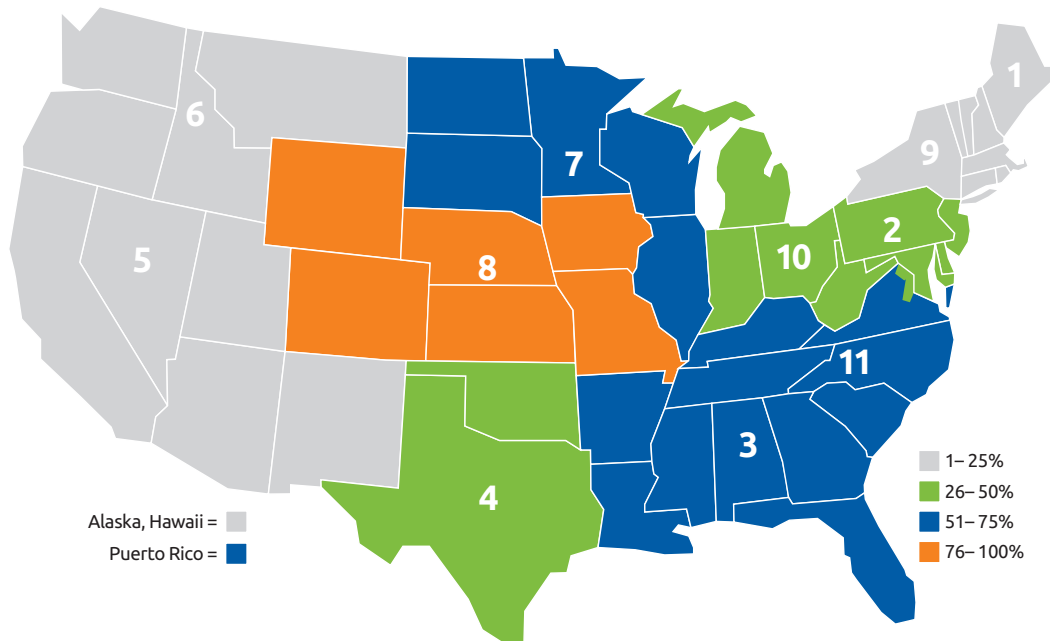
In Regions 1, 5, 6 and 9, more than half of the respondents favored a 4-district map, while 25% or fewer respondents in regions 3, 7, 8, 10, and 11 favored that alternative (Fig 5B).

Figure 5C: 8 Districts



More than half of the respondents in Regions 5 and 10 favored an 8-district map, while 25% or fewer of the respondents in regions 7, 8, and 11 favored it (Fig 5C).

Figure 5D: No Change



More than half of the respondents in Regions 3, 7, 8 and 11 indicated that no change to liver distribution was needed, while 25% or fewer of the respondents in regions 1, 5, 6, and 9 provided that response (Fig 5D).

Question 6.

“My level of concern about the following factors in increasing the size of the distribution areas can be ranked as such:”

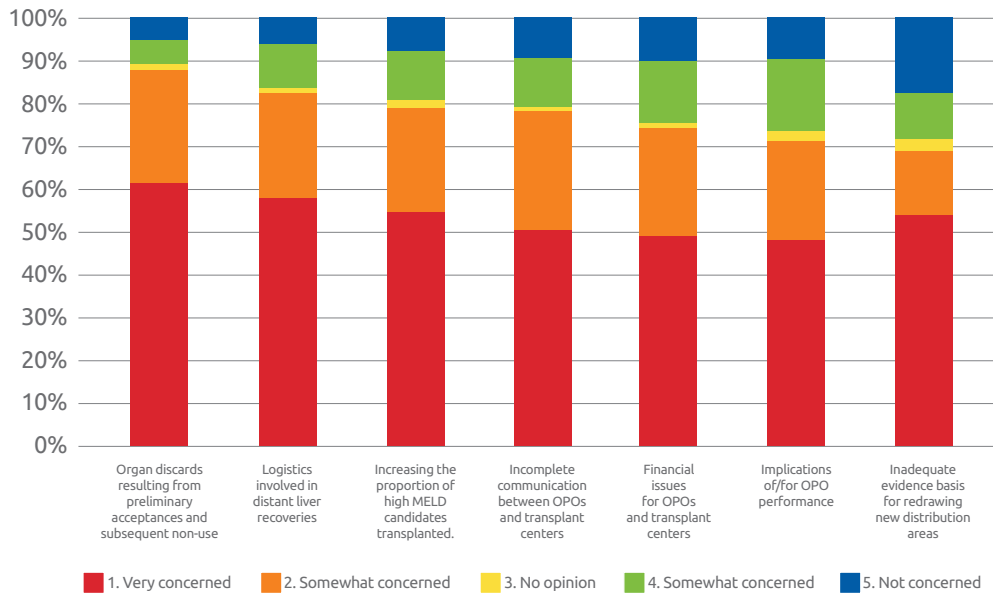


Figure 6 details how concerned respondents are about various factors associated with increasing the size of the liver distribution areas. Over 87% were concerned about organ discards and over 83% were concerned with logistics. More than 70% were concerned with an increasing proportion of high MELD recipients, incomplete communication between OPOs and transplant centers, financial issues, and OPO performance. Nearly 70% of the respondents felt that there was inadequate evidence basis for redrawing new distribution areas.

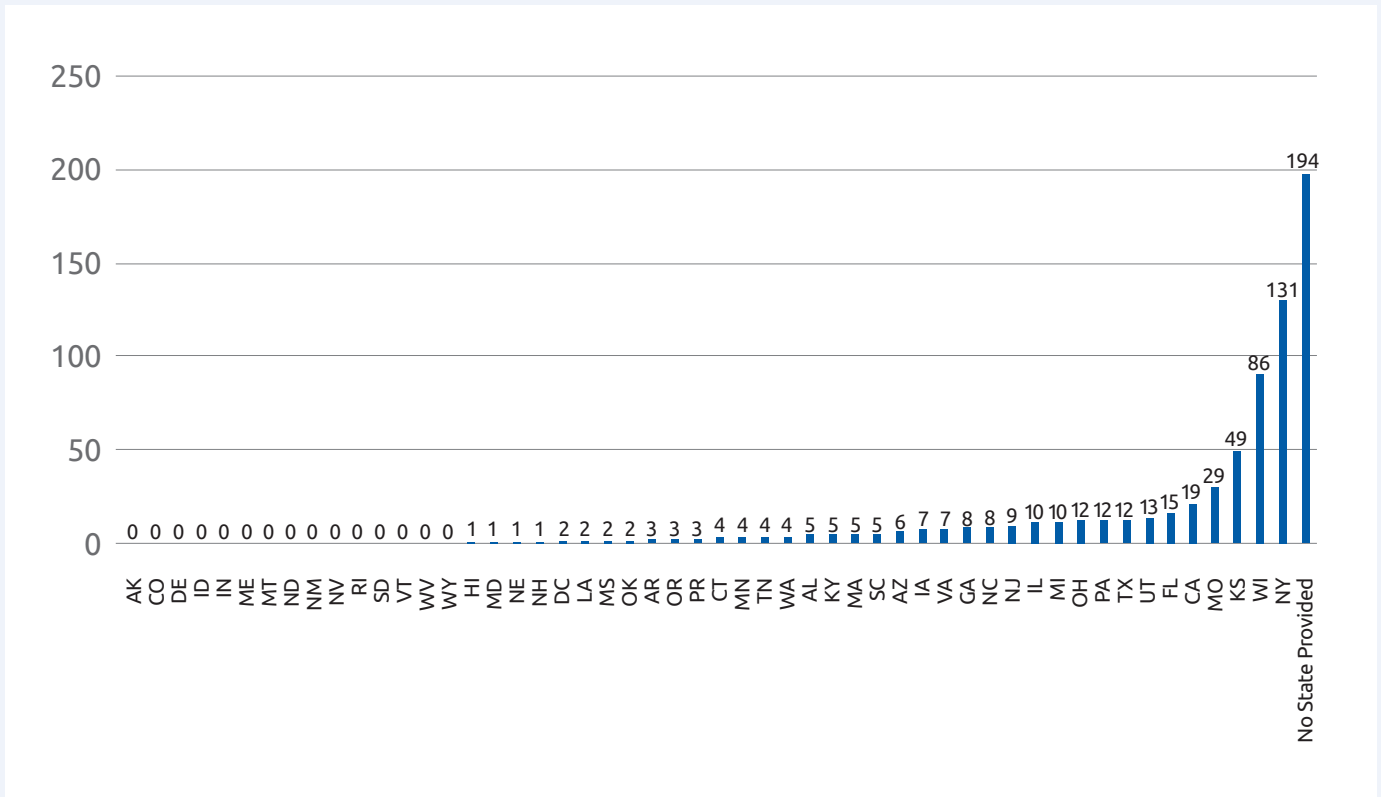
Analysis of Text Responses

Over 1,500 responses to open-ended questions were received. Several common themes emerged in the analysis of this feedback. Those themes were: .

- A need to examine and fully understand the impact of Share 35 before making any changes to the system;
- A need to focus instead on donation rates and public education;
- The impact of OPO performance and the need to reduce the variation in productivity across the nation;
- Concerns about increasing costs and logistics with broader distribution;
- The need to solve some of the current issues with HCC candidates and the Regional Review Boards.

Other responders expressed interest in having the committee pursue other solutions, such as organ distribution systems based on concentric circles, or a phased-in approach to redistricting. The committee is addressing some of these concerns, such as HCC and the standardization of the Regional Review Boards, in separate policy projects.

Appendix A: Number of Responses by State



Appendix B: Questionnaire

1. The ability of all liver transplant candidates to receive timely access to liver transplantation is a component of a fair national organ transplant system.
- Strongly Agree Somewhat Agree Neutral
 Somewhat Disagree Strongly Disagree

2. Addressing the geographic disparity in liver distribution should be a top priority for the OPTN.
- Strongly Agree Somewhat Agree Neutral
 Somewhat Disagree Strongly Disagree

3. If the current distribution system were to change, how important are the following goals? (Very important, Somewhat important, Neutral, Somewhat unimportant, Very unimportant)
- ___ Reducing how much the severity of illness varies among all liver candidates at the time of transplant (for example, reducing variance of MELD/PELD scores at time of transplant)
___ Fewer deaths on the waitlist
___ Maximum transplant survival benefit
___ Optimal quality of life for liver recipients
___ Maximum number of patients transplanted

4. In an effort to achieve these goals, I support creating larger distribution areas, as long as the proposal addressed issues such as cost, cold ischemia time, inappropriate discards, and other operational challenges.
- Strongly Agree Somewhat Agree Neutral
 Somewhat Disagree Strongly Disagree

5. I would support developing revised policy that uses geographic allocation units (yes/no response for each):
- ___ Fewer than 4 Districts
___ 4 Districts
___ 8 Districts
___ Other (please describe in response to question 7)
___ No change needed

6. My level of concern about the following factors in increasing the size of distribution areas can be ranked as such:

Organ discards resulting from preliminary acceptances and subsequent non-use

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

Logistics involved in distant liver recoveries

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

Financial issues for OPOs and transplant centers

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

Implications of/for OPO performance

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

Incomplete communication between OPOs and transplant centers

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

Inadequate evidence basis for redrawing new distribution areas

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

Increasing the proportion of high MELD candidates transplanted, potentially reducing total life years possible for the candidate population as a whole

- Very Concerned Somewhat Concerned
 Somewhat Unconcerned Not at all Concerned

7. The Liver Committee has analyzed the utility of several models to accomplish greater equity and less disparity in liver distribution. Please describe your support of any other potential solutions that should also be considered.

8. What observations and lessons can the OPTN learn from previous changes to liver distribution policy to increase equity in access for wait-listed candidates (For example, Share 35)?

9. Please describe any other concerns or comments related to the concepts put forward in this concept document.

To help the Liver Committee understand the context for certain aggregated responses, please also identify your institution. No institution-identified responses will be released to the Liver Committee or the public.

10. State of residence _____

11. Please identify your affiliation:

- Organ Procurement Organization
 Transplant Hospital
 Other OPTN member Organization
 Patient or patient family
 Other Public
 Prefer not to disclose

12. Institution (only if you answered OPO, TX Hospital, or Other OPTN member organization above)
